



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

7 8 3 5 '03 NOV -3 P1:25

OCT 15 2003

Mr. David Kropp
Director, Regulatory and Consumer Affairs
Pharmavite LLC
P.O. Box 9606
Mission Hills, CA 91346-9606

Dear Mr. Kropp:

This is in response to your letter of September 9, 2003 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Your letter states that the following statement will be used in one or more brands of Essential Balanced Omega 3/6 or other products containing omega 3 (from tuna oil concentrate) as a dietary ingredient: "...helping to maintain normal blood pressure." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood pressure; that is, a claim that does not establish that the claims are about blood pressure that is already within normal limits implies that the product is intended to treat elevated blood pressure (hypertension), which is a disease. Therefore, because the claim you are making for these products represents that the products are intended to affect blood pressure but does not also include a statement about them being intended to affect blood pressure that is already in the normal range, it is an implied disease claim.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for these products suggest that they are intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike,

975-0163

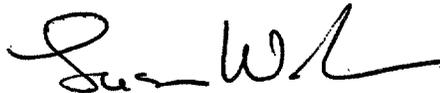
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Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Walker". The signature is fluid and cursive, with a long horizontal stroke at the end.

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240



RECEIVED
9/30/03

September 9, 2003

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

Pharmavite Reference: 9609 P20AB

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) Name and address of manufacturer:
Pharmavite LLC, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):
Omega 3 helps support blood flow to maintain a beautiful skin. Omega 3 supports hydration for dry skin.

Omega 3 helps support cardiovascular health by helping to maintain normal blood pressure.
- (3) Name of the dietary ingredient(s) if not provided in the text of the statement:
Omega 3 (from Tuna Oil Concentrate)
- (4) Name of the dietary supplement:
Essential Balanced Omega 3/6 or products containing above ingredient as a single ingredient or in combination with other ingredients

The above statement(s) may be used in one or more of the following brands of products: B.J.'s Wholesale, Kirkland Signature, Nature Made, Nature's Resource, Nutri Plus, Olay, Spring Valley, Target, TruNature, Walgreens.

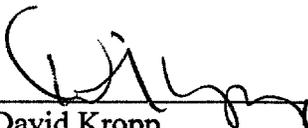
mlf



Re: 9609 P20AB
September 9, 2003
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We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,



David Kropp
Director, Regulatory and Consumer Affairs

cc. P. Bolar